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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/811,055	03/26/2004	John B. Cline	1626-309	7598
25881	7590	06/11/2007	EXAMINER	
EPSTEIN DRANGEL BAZERMAN & JAMES, LLP			BOGART, MICHAEL G	
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SUITE 820			3761	
NEW YORK, NY 10165				
MAIL DATE		DELIVERY MODE		
06/11/2007		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	10/811,055	CLINE, JOHN B.
	Examiner Michael G. Bogart	Art Unit 3761

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 19 January 2007 & 05 June 2007.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 35-60 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 35-60 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 26 March 2004 is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
  1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 5) <input type="checkbox"/> Notice of Informal Patent Application |
|  | 6) <input type="checkbox"/> Other: _____                          |

## DETAILED ACTION

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 35-60 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-17 of copending Application No. 11/430,542. Although the conflicting claims are not identical, they are not patentably distinct from each other because the '542 application claims every material limitation of the instant invention.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

#### *Claim Rejections – 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 35, 47-52, 54, 59 and 60 are rejected under 35 U.S.C. § 102(b) as being anticipated by McDonnell (US 4,121,589).

Regarding claims 35, 59 and 60, McDonnell teaches a device (10) capable of sealing a stoma, said device (10) being situated entirely externally to the body and comprising recess defining means (15); means (1) capable of securing said recess defining means (15) to the body proximate the stoma; and means (16) capable of covering a stoma, situated within said recess

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defining means (15), and comprising a continuous, uninterrupted member that in combination with recess defining means (15) is capable of preventing liquid and/or solid material from exiting the stoma, said recess defining means (15) defining, with said stoma covering means (16), a chamber (17a), said chamber (17a) being situated over said stoma covering means (16) and pressurizable (cap (15) may be pressed by hand) to press said stoma covering means (16) against a stoma (see figure 1 & 3, infra).

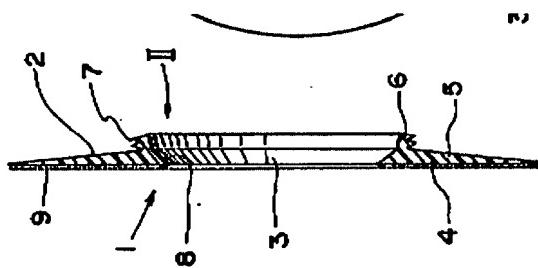


Fig. 1.

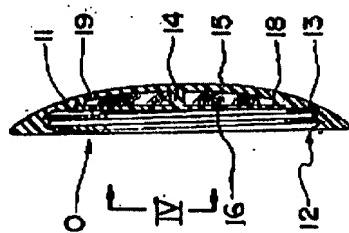


Fig. 3.

Regarding the limitations concerning what the device and its subcomponents do, e.g., "for sealing a stoma", "means for securing", etc., these are functional limitations. Apparatus claims must be structurally distinguishable over the prior art. MPEP § 2114.

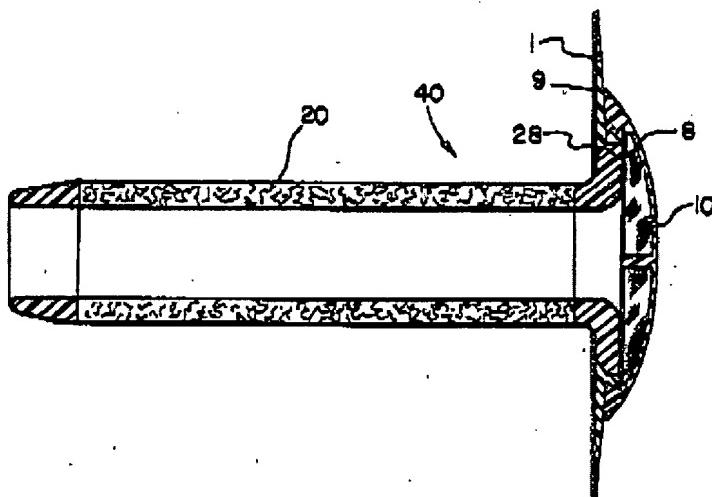
Regarding claim 47, McDonnell teaches venting means (19) in said recess defining means (15).

Regarding claim 48, McDonnell teaches an outlet port (19) and gas filtration means (col. 4, lines 27-39).

Regarding claim 49, McDonnell teaches additional chambers (17b-17d) filled with gas absorbent.

Regarding claims 50 and 51, McDonnell teaches that the securing means (1) includes removably engaging means (7) and adhesive means (9).

Regarding claims 52 and 54, McDonnell teaches a waste collection means (20) attached to the securing means (1)(see fig. 7, infra).



#### *Claim Rejections – 35 USC § 103*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 103 that form the basis for the rejections under this section made in this Office action:

The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

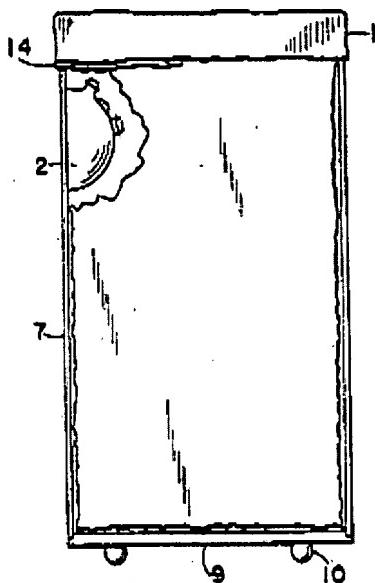
(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 53, 55 and 58 are rejected under 35 U.S.C. § 103(a) as being unpatentable over McDonnell as applied to claims 35, 47-51, 59 and 60 above, and further in view of Cornwell (US 5,195,635 A).

McDonnell does not teach the use of the ostomy device with a collection pouch.

Cornwell teaches an elongated, collapsible pouch (1) for disposing of infectious medical wastes (see fig. 5, infra).

FIG. 5

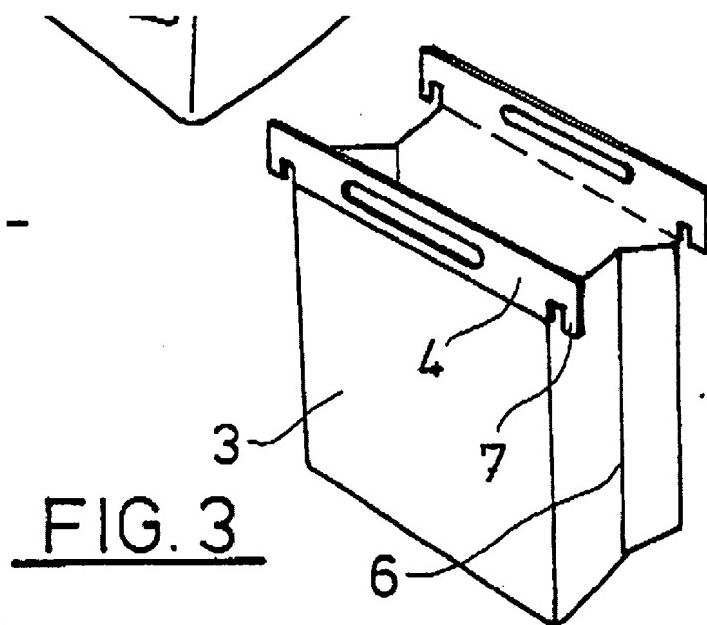


At the time of the invention, it would have been obvious for one of ordinary skill in the art to use the medical waste pouch of Cornwell to dispose of the device of McDonnell in order to provide a means of safely disposing of the device after use.

Claims 56 are rejected under 35 U.S.C. § 103(a) as being unpatentable over McDonnell as applied to claims 35, 47-51, 59 and 60 above, and further in view of Bergmann *et al.* (DE 43 40 705 A1; hereinafter: "Bergmann").

McDonnell does not disclose expressly that the device can be used with waste collection means having a concertina-like configuration.

Bergmann teaches a waste bag (4) having a concertina configuration (see English language abstract)(see fig. 3, infra).

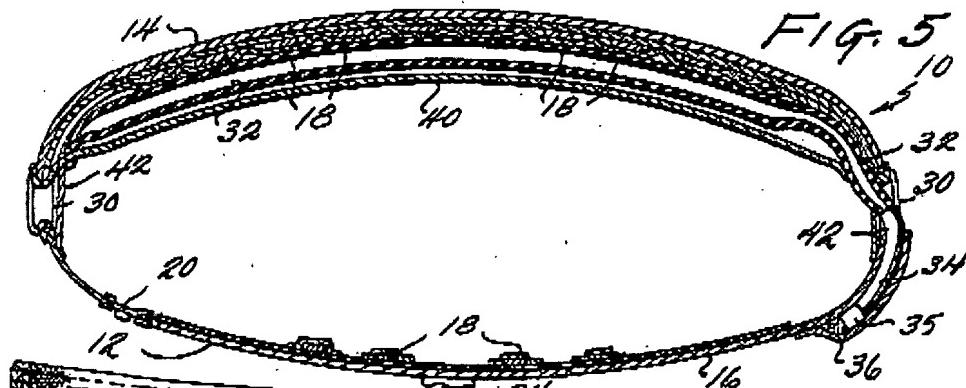


At the time of the invention, it would have been obvious for one of ordinary skill in the art to use the medical waste pouch of Bergmann to dispose of the device of McDonnell in order to provide a means of conveniently disposing of the device after use.

Claims 35-41, 46, 52, 57, 59 and 60 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Eisen (US 3,071,133) in view of Schreiber (US 3,052,236).

Regarding claims 35, 59 and 60, Eisen teaches a device (10) capable of sealing a stoma, said device (10) being situated entirely externally to the body and comprising recess defining means (14); means (30, 42) capable of securing said recess defining means (14) to the body proximate the stoma; and means (inner or body-facing layer of bladder (32) and liner (40)) capable of covering a stoma, situated within said recess defining means (14), and comprising a continuous, uninterrupted member (inner layer of bladder (32) and liner (40)) that is capable of occluding a stoma when it is pressed against a stoma, said recess defining means (14) defining, with said stoma covering means, a chamber (32), said chamber being situated over said stoma

covering means and pressurizable to press said stoma covering means against a stoma (1)(col. 1, line 66-col. 2, line 25)(see figure 5, infra).



Regarding the limitations concerning what the device and its subcomponents do, e.g., "for sealing a stoma", "means for securing", etc., these are functional limitations. Apparatus claims must be structurally distinguishable over the prior art. MPEP § 2114.

Eisen does not disclose expressly that the bladder walls are capable of preventing passage of liquid and/or solid material. Eisen does teach that the bladder is inflatable which suggests that it is made of material that impedes passage of gasses.

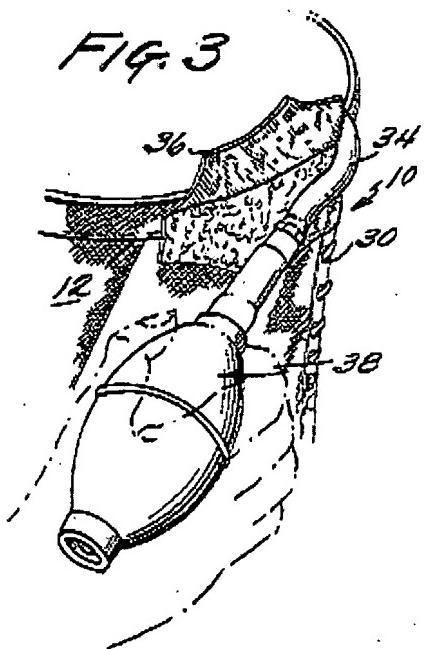
Schrieber teaches a belt with inflatable bladder (14) that is made of rubber such that it inherently impervious to gases in addition to solid or liquid human wastes (col. 2, lines 40-51).

At the time of the invention, it would have been obvious to one of ordinary skill in the art to make Eisen's bladder walls out of the rubber material taught by Schrieber in order to provide materials that are known in the art to be gas impervious so that the bladder can retain an inflated configuration.

Regarding claim 36, Schrieber teaches a flexible bladder (14) which is made of rubber (col. 2, lines 40-51).

Regarding claim 37, Eisen teaches that bladder (32) bodyside layer and liner (40) are fixed to the interior of recess defining means (14)(see fig. 5, supra).

Regarding claims 38-40, Eisen teaches pressurizing (38) means including a neck (34) and a valve (col. 2, lines 8-19)(see fig. 3, infra).



Regarding claim 41, Eisen teaches a pump (38). Merely making the pump integral with recess defining means is not sufficient to patentably distinguish the invention over the prior art.

*In re Larson*, 340 F.2d 965, 968, 144 USPQ 347, 349 (CCPA 1965). MPEP § 2144.04.

Regarding claim 46, Eisen teaches an external pressurization device (38).

Regarding claim 52, Eisen teaches a pocket (40) that can be used to collect waste.

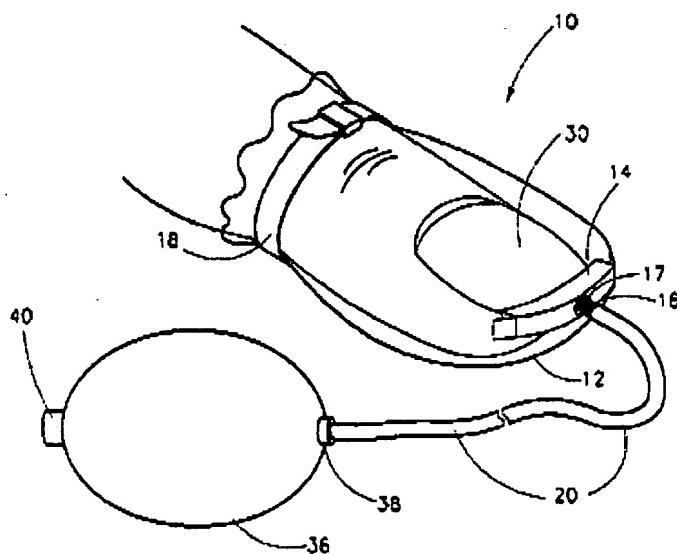
Regarding claim 57, Eisen teaches a pouch (40) having ends fixed between recess defining means (14) and securing means (30)(see fig. 5).

Claims 42-45 and 47 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Eisen and Schrieber as applied to claims 35-41, 46, 59 and 60 above, and further in view of Berenstein (US 5,795,314 A).

Eisen does not expressly disclose that the pump is flexible.

Berenstein teaches a handpump (40) that is flexible so as to allow it to pump air (col. 3, lines 9-19)(see fig. 1, infra).

At the time of the invention, it would have been obvious to one of ordinary skill in the art to make the pump of Eisen and Schrieber flexible in the manner taught by Berenstein in order to provide a manual pump that is recognized in the art as being suitable for pumping air to a wearable article.



Regarding claim 43, Eisen teaches a check valve (col. 2, lines 14-19).

Regarding claims 44, 45 and 47, Berenstein teaches a pressure-limiting or relief valve or vent (22).

***Response to Arguments***

Applicant's arguments with respect to claims 35-47, 51-53, 55, 56 and 58 have been considered but are moot in view of the new ground(s) of rejection.

Applicants have not addressed the obvious-type double patenting rejection of claims 1-58 over application serial number 11/430,542.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Bogart whose telephone number is (571) 272-4933.

In the event the examiner is not available, the Examiner's supervisor, Tatyana Zalukaeva may be reached at phone number (571) 272-1115. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300 for formal communications. For informal communications, the direct fax to the Examiner is (571) 273-4933.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-3700.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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*MB*  
Michael Bogart  
6 June 2007

TATYANA ZALUKAEVA  
SUPERVISORY PRIMARY EXAMINER

*Tatya*